EXELIXIS INC
Form 10-Q
May 03, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 30, 2012

Or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 000-30235

Exelixis, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	04-3257395
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

210 East Grand Ave.

South San Francisco, CA 94080

(Address of Principal Executive Offices) (Zip Code)

(650) 837-7000

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of April 27, 2012, there were 148,476,783 shares of the registrant s common stock outstanding.

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EXELIXIS, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED MARCH 30, 2012

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

EXELIXIS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2012 (unaudited)	December 31, 2011 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,466	$ 74,257
Marketable securities	172,979	120,005
Other receivables	1,930	30,190
Prepaid expenses and other current assets	4,641	4,372
Total current assets	250,016	228,824
Restricted cash and investments	4,199	4,199
Long-term investments	84,470	85,260
Property and equipment, net	7,326	8,506
Goodwill	63,684	63,684
Other assets	2,905	2,789
Total assets	$ 412,600	$ 393,262
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,878	$ 1,957
Accrued clinical trial liabilities	21,634	21,729
Accrued compensation and benefits	6,586	8,943
Other accrued liabilities	8,218	8,423
Current portion of notes payable and bank obligations	4,015	4,870
Current portion of convertible loans	10,000	
Current portion of restructuring	3,875	4,483
Deferred revenue	31,253	41,920
Total current liabilities	87,459	92,325
Long-term portion of notes payable and bank obligations	84,470	85,260
Long-term portion of convertible loans	83,578	91,385
Long-term portion of restructuring	8,481	9,495
Other long-term liabilities	7,755	7,844
Deferred revenue	8,508	16,321
Total liabilities	280,251	302,630
Commitments		
Stockholders equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized; issued and outstanding:		

148,457,650 and 135,563,735 shares at March 31, 2012 and December 31, 2011, respectively:	148	135
Additional paid-in-capital	1,264,659	1,196,992
Accumulated other comprehensive income (loss)	50	(138)
Accumulated deficit	(1,132,508)	(1,106,357)
Total stockholders equity	132,349	90,632
Total liabilities and stockholders equity	$ 412,600	$ 393,262

(1) The condensed consolidated balance sheet at December 31, 2011 has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

The accompanying notes are an integral part of these condensed consolidated financial statements.

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EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(unaudited)

	Three Months Ended March 31,	
	2012	2011
Revenues:		
Contract	$ 3,831	$ 12,410
License	14,679	22,789
Collaboration reimbursement		694
Total revenues	18,510	35,893
Operating expenses:		
Research and development	33,096	45,691
General and administrative	7,905	9,165
Restructuring (credit) charge	(195)	4,767
Total operating expenses	40,806	59,623
Loss from operations	(22,296)	(23,730)
Other income (expense):		
Interest income and other, net	160	183
Interest expense	(4,004)	(3,943)
Total other income (expense), net	(3,844)	(3,760)
Loss before income taxes	(26,140)	(27,490)
Income tax provision	(11)	
Net loss	$ (26,151)	$ (27,490)
Net loss per share, basic and diluted	$ (0.18)	$ (0.24)
Shares used in computing basic and diluted loss per share amounts	141,940	113,215

EXELIXIS, INC.

CONSOLIDATED STATEMENTS OF OTHER COMPREHENSIVE LOSS

(in thousands)

(unaudited)

	$(0,00)	$(0,00)

	Three Months Ended March 31,	
	2012	2011
Net loss	$ (26,151)	$ (27,490)
Net unrealized gains (losses) on available-for-sale securities	188	(43)
Comprehensive loss	$ (25,963)	$ (27,533)

Accumulated other comprehensive income consisted solely of unrealized gains (losses) on available for sale securities for the periods presented.

The accompanying notes are an integral part of these condensed consolidated financial statements.

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EXELIXIS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	$ (26,151)	$ (27,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,233	1,929
Stock-based compensation expense	2,332	3,603
Restructuring (credit) charge for property and equipment	(195)	122
Accretion of debt discount	2,193	1,878
Other	1,304	478
Changes in assets and liabilities:		
Other receivables	27,870	125
Prepaid expenses and other current assets	(268)	(1,279)
Other assets	(116)	114
Accounts payable and other accrued expenses	(2,736)	4,351
Restructuring liability	(1,865)	(1,478)
Other long-term liabilities	(87)	(232)
Deferred revenue	(18,480)	(25,397)
Net cash used in operating activities	(14,966)	(43,276)
Cash flows from investing activities:		
Purchases of property and equipment	(72)	(405)
Proceeds from sales of property and equipment	847	
Decrease in restricted cash and investments		2,200
Proceeds from maturities of marketable securities	60,315	26,718
Purchases of marketable securities	(113,368)	(60,015)
Net cash used in investing activities	(52,278)	(31,502)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of offering costs	64,990	179,347
Proceeds from exercise of stock options and warrants, net of repurchases	109	3,794
Principal payments on notes payable and bank obligations	(1,646)	(3,752)
Net cash provided by financing activities	63,453	179,389
Net (decrease) increase in cash and cash equivalents	(3,791)	104,611
Cash and cash equivalents, at beginning of period	74,257	97,440
Cash and cash equivalents, at end of period	$ 70,466	$ 202,051

The accompanying notes are an integral part of these condensed consolidated financial statements.

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EXELIXIS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2012

(unaudited)

NOTE 1. Organization and Summary of Significant Accounting Policies

Organization

Exelixis, Inc. (Exelixis, we, our or us) is a biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development efforts exclusively on cabozantinib (XL184), our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by U.S. generally accepted accounting principles (GAAP) for complete financial statements. In our opinion, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the period presented have been included. Certain reclassifications of prior period amounts have been made to our condensed consolidated financial statements to conform to the current period presentation.

Exelixis adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. Fiscal year 2011, a 52-week year, ended on December 30, 2011, and fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal quarters ended April 1, 2011 and March 30, 2012, and as of the fiscal year ended December 30, 2011, are indicated as ended March 31, 2011 and 2012, and as ended December 31, 2011, respectively.

Operating results for the three-month period ended March 31, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 28, 2012 or for any future period. These financial statements and notes should be read in conjunction with the consolidated financial statements and notes thereto for the fiscal year ended December 30, 2011 included in our Annual Report on Form 10-K filed with the SEC on February 22, 2012.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated.

Use of Estimates

The preparation of the consolidated financial statements is in conformity with GAAP, which requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, clinical trial accruals, restructuring liability and stock option valuation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Cash and Investments

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. We invest in high-grade, short-term commercial paper and money market funds, which are subject to minimal credit and market risk.

All marketable securities are classified as available-for-sale and are carried at fair value. We view our available-for-sale portfolio as available for use in current operations. Accordingly, we have classified certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale securities are stated at fair value based upon quoted market prices of the securities. We have classified certain investments as cash and cash equivalents or marketable securities that collateralize loan balances; however, they are not restricted to withdrawal. Funds that are used to collateralize equipment lines of credit that extend for over 12 months have been classified as long-term investments, in association with the loan arrangement. Unrealized gains and losses on available-for-sale investments are reported as a separate component of stockholders equity. Realized gains and losses, net, and interest and dividends on available-for-sale securities are recorded in our Condensed Consolidated Statement of Operations as Interest income and other, net. The cost of securities sold is based on the specific identification method.

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All of our marketable securities are subject to quarterly reviews for impairment that is deemed to be other-than-temporary. An investment is considered other-than-temporarily impaired when its fair value is below its amortized cost and (1) we intend to sell the security, (2) it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis or (3) the present value of expected cash flows from the investment is not expected to recover the entire amortized cost basis.

The following summarizes available-for-sale securities as of March 31, 2012 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 35,228	$	$	$ 35,228
Commercial paper	96,753	18	(3)	96,768
Corporate bonds	110,795	65	(40)	110,820
U.S. Government sponsored enterprises	65,638	13	(2)	65,649
Municipal bonds	23,650		(1)	23,649
Total	$ 332,064	$ 96	$ (46)	$ 332,114

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As reported:				
Cash equivalents	$ 70,465	$ 1	$	$ 70,466
Marketable securities	172,930	95	(46)	172,979
Restricted cash and investments	4,199			4,199
Long-term investments	84,470			84,470
Total	$ 332,064	$ 96	$ (46)	$ 332,114

As of March 31, 2012, all securities that were in an unrealized loss position have been so for less than one year and the unrealized losses were due to market conditions and were not attributed to credit risk. Based on the scheduled maturities of our marketable securities, we concluded that the unrealized losses in our investment securities are not other-than-temporary, as it is more likely than not that we will hold these investments for a period of time sufficient for a recovery of our cost basis.

The following summarizes available-for-sale securities as of December 31, 2011 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 81,986	$	$	$ 81,986
Commercial paper	29,079	2	(1)	29,080
Corporate bonds	116,068	22	(169)	115,921
U.S. Government sponsored enterprises	37,237	12		37,249
Municipal bonds	19,488		(3)	19,485
Total	$ 283,858	$ 36	$ (173)	$ 283,721

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value

As reported:				
Cash equivalents	$ 74,256	$ 1	$	$ 74,257
Marketable securities	120,143	35	(173)	120,005
Restricted cash and investments	4,199			4,199
Long-term investments	85,260			85,260
Total	$ 283,858	$ 36	$ (173)	$ 283,721

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The following summarizes available-for-sale securities as of March 31, 2012 by contractual maturity (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Mature in less than one year	$ 311,877	$ 89	$ (40)	$ 311,926
Mature in one to two years	20,187	7	(6)	20,188
Total	$ 332,064	$ 96	$ (46)	$ 332,114

The following summarizes available-for-sale securities as of December 31, 2011 by contractual maturity (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Mature in less than one year	$ 259,209	$ 24	$ (151)	$ 259,082
Mature in one to two years	24,649	12	(22)	24,639
Total	$ 283,858	$ 36	$ (173)	$ 283,721

Fair Value Measurements

The fair value of our financial instruments reflects the amounts that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy has the following three levels:

Level 1 quoted prices in active markets for identical assets and liabilities.

Level 2 observable inputs other than quoted prices in active markets for identical assets and liabilities.

Level 3 unobservable inputs.

Our financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The Level 2 inputs were determined using prices from independent pricing services based on quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets. There were no transfers between Level 1 and Level 2 of the fair value hierarchy, as determined at the end of each reporting period. The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of March 31, 2012 and December 31, 2011, respectively (in thousands):

As of March 31, 2012:

	Level 1	Level 2	Level 3	Total
Money market funds	$ 35,228	$	$	$ 35,228
Commercial paper		96,768		96,768
Corporate bonds		110,820		110,820
U.S. Government sponsored agencies		65,649		65,649
Municipal bonds		23,649		23,649
Total	$ 35,228	$ 296,886	$	$ 332,114

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As of December 31, 2011:

	Level 1	Level 2	Level 3	Total
Money market funds	$ 81,986	$	$	$ 81,986
Commercial paper		29,080		29,080
Corporate bonds		115,921		115,921
U.S. Government sponsored agencies		37,249		37,249
Municipal bonds		19,485		19,485
Total	$ 81,986	$ 201,735	$	$ 283,721

We have estimated the fair value of our long-term debt instruments, where possible, using the net present value of the payments discounted at an interest rate that is consistent with money-market rates that would have been earned on our non-interest-bearing compensating balances, which is a Level 2 input. However, due to the unique structure of our 2010 financing agreement with entities affiliated with Deerfield Management Company L.P. (Deerfield) and the current non-liquid market in structured notes, there is no practicable method to determine the fair value of this instrument. See Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Cash Requirements for details on the structure and terms of our 2010 financing with Deerfield. The estimated fair value of our outstanding debt, excluding our 2010 financing with Deerfield, was as follows (in thousands):

	March 31, 2012	December 31, 2011
Equipment lines of credit	$ 8,430	$ 10,066
Silicon Valley Bank loan	77,884	77,835
Total	$ 86,314	$ 87,901

At March 31, 2012 and December 31, 2011, the book value of our debt outstanding, including our 2010 financing with Deerfield, was $182.1 million and $181.5 million, respectively. Our payment commitments associated with these debt instruments are fixed during the corresponding terms and comprise interest payments, principal payments or a combination thereof. The fair value of our debt will fluctuate with movements of interest rates, increasing in periods of declining rates of interest, and declining in periods of increasing rates of interest.

Long Lived Assets

The carrying value of our long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Long-lived assets include property and equipment and identified intangible assets. In the quarters ended March 31, 2012 and March 31, 2011, we recorded impairment charges associated with our property and equipment in the amount of approximately $0.2 million and $0.1 million, respectively, in connection with our 2010 and 2011 restructurings. See Note 4 to the Condensed Consolidated Financial Statements for further information on the restructurings.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash and cash equivalents, accounts receivable and investments in marketable securities. Cash equivalents and marketable securities consist of money market funds, taxable commercial paper, corporate bonds with high credit quality, obligations of U.S. government sponsored enterprises and municipal bonds. All cash and cash equivalents and marketable securities are maintained with financial institutions that management believes are creditworthy. Other receivables are typically unsecured and are concentrated in the pharmaceutical and biotechnology industries. Accordingly, we may be exposed to credit risk generally associated with pharmaceutical and biotechnology companies. We have incurred no bad debt expense since inception.

Net Loss Per Share

Basic and diluted net loss per share are computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share excludes potential common stock because its effect is antidilutive. Potential common stock consists of incremental common shares issuable (1) upon the exercise of stock options and warrants, (2) in connection with vesting of restricted stock units (RSUs), (3) pursuant to our employee stock purchase plan, and (4) upon conversion of our loan with GlaxoSmithKline, which was fully repaid in 2011.

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As of March 31, 2012 and 2011, our potential common stock includes the following shares, all of which have been excluded from the computation of diluted net loss per share because their impact is antidilutive:

	March 31, 2012	March 31, 2011
Restricted stock units, common stock options and employee stock purchase plan	18,381,935	19,767,091
Conversion of loan		3,153,729
Warrants	1,441,215	2,250,000
Total antidilutive shares	19,823,150	25,170,820

Collaboration Arrangements

Collaborative agreement reimbursement revenues are recorded as earned or owed based on the performance requirements by both parties under the respective contracts. For the quarter ended March 31, 2011, reimbursement payments were presented as collaboration reimbursement revenues. There were no such reimbursements for the quarter ended March 31, 2012, and we do not expect to record any further collaboration reimbursement revenues under our current collaborations.

Foreign Currency Translation and Remeasurement

Assets and liabilities denominated in currencies other than the functional currency are remeasured using exchange rates in effect at the end of the period and related gains or losses are recorded in interest income and other, net. Gains and losses on the remeasurement of foreign currency assets and liabilities were not material for the periods presented.

Recently Adopted Accounting Pronouncements

In December 2011, Accounting Standards Codification Topic 350, *Testing Goodwill for Impairment* was amended to allow the option of performing a qualitative assessment in evaluating goodwill for impairment. We adopted this guidance beginning January 1, 2012, and it did not have a material effect on our consolidated financial statements.

In May 2011, Accounting Standards Codification Topic 820, *Fair Value Measurement* was amended to converge U.S. and international accounting standards and provide more detailed disclosure. We adopted this guidance beginning January 1, 2012 and added additional disclosure as required. The amendment it did not have a material effect on our consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2011, Accounting Standards Codification Topic 210, *Balance Sheet* was amended to converge U.S. and international accounting standards, and requires additional disclosure about offsetting of financial instruments. This guidance will be effective January 1, 2013 and we are evaluating the effect on our consolidated financial statements.

NOTE 2. Stock-Based Compensation

We recorded and allocated employee stock-based compensation expenses as follows (in thousands):

	Three Months Ended March 31, 2012	2011
Research and development expense	$ 1,207	$ 1,748
General and administrative expense	1,097	1,332
Restructuring-related stock compensation expense		449

Total employee stock-based compensation expense	$ 2,304	$ 3,529

We use the Black-Scholes option pricing model to value our stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. We considered implied volatility as well as our historical volatility in developing our estimate of expected volatility. The fair value of employee share-based payments awards was estimated using the following assumptions and weighted average fair values:

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	Stock Options Three Months Ended March 31,		Employee Stock Purchase Plan Three Months Ended March 31,	
	2012	2011 (1)	2012	2011
Weighted average grant date fair value	$ 2.91	$ N/A	$ 2.61	$ 1.47
Risk-free interest rate	1.00%	N/A	0.05%	0.16%
Dividend yield	0%	N/A	0%	0%
Volatility	65%	N/A	68%	65%
Expected life	5.2 years	N/A	0.5 years	0.5 years

(1) No options were granted during the three months ended March 31, 2011.

A summary of all stock option activity for the three months ended March 31, 2012 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2011	17,436,378	$ 7.16		
Granted	66,175	5.26		
Exercised	(22,031)	4.97		
Cancelled	(397,104)	11.89		
Options outstanding at March 31, 2012	17,083,418	$ 7.04	4.69 years	$ 617,036
Exercisable at March 31, 2012	13,278,874	$ 7.38	4.15 years	$ 502,674

As of March 31, 2012, $9.6 million of total unrecognized compensation expense related to employee stock options was expected to be recognized over a weighted-average period of 2.72 years.

A summary of all RSU activity for the three months ended March 31, 2012 is presented below:

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
RSUs outstanding at December 31, 2011	1,391,691	$ 6.92		
Awarded	18,734	5.27		
Released	(288,161)	7.31		
Forfeited	(18,387)	7.45		
RSUs outstanding at March 31, 2012	1,103,877	$ 6.79	1.37 years	$ 5,718,083

As of March 31, 2012, $5.7 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 2.45 years.

NOTE 3. Collaborations

Merck

On December 21, 2011, we entered into an agreement with Merck & Co., Inc., known as MSD outside of the United States and Canada (Merck), pursuant to which we granted to Merck an exclusive worldwide license to our phosphoinositide-3 kinase delta (PI3K-d) program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck will have sole responsibility to research, develop, and commercialize compounds from our PI3K-d program. As a result we recognized $1.3 million in revenue in December 2011.

Merck was required to pay us an up-front cash payment of $12.0 million in connection with the agreement, which we received on January 19, 2012. Under the terms of the agreement, we completed the transfer of the license and associated knowledge within ninety days of the effective date of the agreement and accordingly recognized the remaining unrecognized up-front payment of $10.7 million as of March 31, 2012. We will be eligible to receive potential development and regulatory milestone payments for multiple indications of up to $239.0 million. We will also be eligible to receive combined sales performance milestones of up to $375.0 million and royalties on net-sales of products emerging from the agreement. Milestones and royalties are payable on compounds emerging from our PI3K-d program or from certain compounds that arise from Merck s internal discovery efforts targeting PI3K-d during a certain period.

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Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either of us may terminate the agreement for the other party s uncured material breach. In the event of termination by Merck at will or by us for Merck s uncured material breach, the license granted to Merck would terminate. In the event of a termination by us for Merck s uncured material breach, we would receive a royalty-free license from Merck to develop and commercialize certain joint products. In the event of termination by Merck for our uncured material breach, Merck would retain the licenses from us, and we would receive reduced royalties from Merck on commercial sales of products.

Bristol-Myers Squibb Company

2007 Cancer Collaboration

In December 2006, we entered into a worldwide collaboration with Bristol-Myers Squibb Company (Bristol-Myers Squibb), which became effective in January 2007, to discover, develop and commercialize novel targeted therapies for the treatment of cancer. We were responsible for discovery and preclinical development of small molecule drug candidates directed against mutually selected targets. In January 2007, Bristol-Myers Squibb made an up-front payment of $60.0 million to us for which we granted Bristol-Myers Squibb the right to select up to three investigational new drug (IND) candidates from six future Exelixis compounds. We recognized the up-front payment as revenues over the estimated research term.

For each IND candidate selected, we were entitled to receive a $20.0 million selection milestone from Bristol-Myers Squibb. Once selected, Bristol-Myers Squibb became responsible for leading the further development and commercialization of the selected IND candidates. In addition, we had the right to opt in to co-promote the selected IND candidates, in which case we would equally share all development costs and profits in the United States. In January 2008 and November 2008, Bristol-Myers Squibb exercised its option under the collaboration to develop and commercialize XL139 (BMS-833923), a Hedgehog inhibitor, and XL413 (BMS-863233), a CDC7 inhibitor, respectively. Under the terms of the collaboration agreement, the selection of XL139 and XL413 by Bristol-Myers Squibb entitled us to milestone payments of $20.0 million each, which we received in February 2008 and December 2008, respectively. In addition, we exercised our option under the collaboration agreement to co-develop and co-commercialize each of XL139 and XL413 in the United States.

In September 2010, we and Bristol-Myers Squibb terminated the XL413 program due to an unfavorable pharmacological profile observed in phase 1 clinical evaluation. Additionally, in connection with an amendment to the collaboration which became effective in November 2010, we exercised our right to opt-out of further co-development of XL139 in consideration for a payment of $20.0 million. This opt-out payment and the remaining deferred revenue balance as of the effective date of the opt-out, November 2010, were combined with and recognized in conjunction with the up-front fees received related to our TGR5 license agreement and ROR collaboration agreement entered into with Bristol-Myers Squibb in 2010, and will be recognized over the agreement with the longest term. Please refer to the 2010 Collaboration Agreements within this note.

The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. We have no further responsibility for conducting new activities or funding new development or commercialization activities with respect to XL139 and will therefore no longer be eligible to share profits on sales of any commercialized products under the collaboration. We will continue to be eligible to receive regulatory and commercial milestones as well as double-digit royalties on any future sales of any products commercialized under the collaboration. As a result of the November 2010 amendment to the collaboration, the research term has ended, and we have no further obligation to deliver to Bristol-Myers Squibb a third IND candidate under the collaboration.

2010 Collaboration Agreements

TGR5 License Agreement

In October 2010, we entered into a global license agreement with Bristol-Myers Squibb for XL475 (and any potential backups), a preclinical compound that modulates the metabolic target known as TGR5 (the TGR5 License Agreement). Pursuant to the terms of the TGR5 License Agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and has sole control and responsibility for all subsequent research, development, commercial and manufacturing activities. The TGR5 License Agreement became effective in November 2010 following clearance under the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended. The license agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries.

Under the license agreement, Bristol-Myers Squibb received a worldwide exclusive license to XL475 and sole control and responsibility for all research, development, commercial and manufacturing activities. In November 2010 we received a nonrefundable up-front cash payment of $35.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the license, we will be eligible to receive development and regulatory milestones of up to $250.0 million and commercial milestones of up to $150.0 million, as well as royalties on commercial sales of any such products. As of March 31, 2012, we have recognized aggregate license revenue of $17.1 million under

this agreement.

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ROR Collaboration Agreement

In October 2010, we entered into a worldwide collaboration with Bristol-Myers Squibb pursuant to which each party granted to the other certain intellectual property licenses to enable the parties to discover, optimize and characterize ROR antagonists that may subsequently be developed and commercialized by Bristol-Myers Squibb. In November 2010 we received a nonrefundable up-front cash payment of $5.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the collaboration, we will be eligible to receive development and regulatory milestones of up to $255.0 million and commercial milestones of up to $150.0 million, as well as royalties on commercial sales of any such products. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to one of our wholly-owned subsidiaries. As of March 31, 2012, we have recognized aggregate license revenue of $3.9 million under this agreement.

NOTE 4: Restructurings

During 2010, we implemented two restructurings that resulted in an overall reduction in our workforce of 386 employees. In March 2011, we implemented an additional restructuring that resulted in further reductions in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructurings of 402 employees. The restructurings are a consequence of our decision to focus our proprietary resources and development efforts on the late-stage development and commercialization of cabozantinib.

Since the inception of the 2010 and 2011 restructurings, we have recorded aggregate restructuring charges of $42.7 million, of which $20.2 million related to termination benefits and $22.5 million related to facility charges and the impairment of various assets. We had a restructuring credit of $0.2 million for the three months ended March 31, 2012. The credit was primarily due to asset auctions and direct sales of previously impaired assets, partially offset by facility-related charges due to the exit of all or portions of three of our South San Francisco buildings. The total outstanding restructuring liability is included in Current portion of restructuring and Long-term portion of restructuring on our Condensed Consolidated Balance Sheet and is based upon restructuring charges recognized as of March 31, 2012 in connection with the 2010 and 2011 restructurings. As of March 31, 2012, the components of these liabilities are summarized in the following table (in thousands):

	Employee Severance And Other Benefits	Facility Charges	Asset Impairment	Legal and Other Fees	Total
Ending accrual balance as of December 31, 2011	$ 6	$ 13,921	$	$ 51	$ 13,978
Restructuring (credit) charge	(5)	248	(438)		(195)
Cash payments	(1)	(1,864)			(1,865)
Adjustments or non-cash credits			(409)		(409)
Proceeds from sale of assets			847		847
Ending accrual balance as of March 31, 2012	$	$ 12,305	$	$ 51	$ 12,356

With respect to our restructurings, we expect to incur additional restructuring charges of $1.7 million relating to the previously mentioned exit and sublease of our South San Francisco facilities. These charges will be recorded through the end of 2017, or the end of the building lease terms.

The remaining charges that we expect to incur in connection with the restructurings are subject to a number of assumptions, and actual results may materially differ. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructurings.

NOTE 5. Sale of Shares of Common Stock

In March 2011, we completed a public offering of 17.3 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately $179.3 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

In February 2012, we completed a public offering of 12.7 million shares of our common stock pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received approximately $65 million in net proceeds from

the offering after deducting the underwriting discount and related offering expenses.

NOTE 6: Income Taxes

We recorded an income tax provision of $0.01 million for the three months ended March 31, 2012 for tax-related interest associated with the audit by the Internal Revenue Service of our 2008, 2009 and 2010 tax years.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as believe, anticipate, expect, intend, plan, focus, goal, objective, will, may, could, would, estimate, predict, potential, continue, encouraging, or the negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in Part II, Item 1A of this Form 10-Q, as well as those discussed elsewhere in this report.

This discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this report and the financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, filed with the Securities and Exchange Commission, or SEC, on February 22, 2012. Operating results are not necessarily indicative of results that may occur in future periods. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

We are a biotechnology company committed to developing small molecule therapies for the treatment of cancer. We are focusing our proprietary resources and development efforts exclusively on cabozantinib, or XL184, our most advanced product candidate, in order to maximize the therapeutic and commercial potential of this compound. We believe cabozantinib has the potential to be a high-quality, broadly-active, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. We have also established a portfolio of other novel compounds that we believe have the potential to address serious unmet medical needs, many of which are being advanced by partners as part of collaborations.

Cabozantinib

Cabozantinib inhibits MET, VEGFR2 and RET, proteins that are key drivers of tumor growth, vascularization and/or metastasis. Cabozantinib has shown novel and differentiated activity in multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer, or CRPC, and medullary thyroid cancer but also includes the evaluation of other tumor types. Exelixis has implemented a strategy to investigate cabozantinib in a comprehensive development program for CRPC to potentially generate a product that could effectively compete in the CRPC marketplace. Two phase 3 pivotal trials, COMET-1 (CabOzantinib MET Inhibition CRPC Efficacy Trial-1, formerly known as XL184-307) and COMET-2 (CabOzantinib MET Inhibition CRPC Efficacy Trial-2, formerly known as XL184-306), were designed to provide an opportunity to commercially differentiate cabozantinib as an oncology agent with a potentially beneficial impact on overall survival, pain palliation and narcotic usage. We expect to initiate the COMET-1 trial with an overall survival endpoint in the second quarter of 2012. We initiated the COMET-2 trial with a pain palliation endpoint in December 2011. We also initiated a rolling submission of a new drug application, or NDA, for cabozantinib in medullary thyroid cancer in December 2011 following our October 2011 announcement of the top-line results of the primary endpoint of our ongoing phase 3 clinical trial of cabozantinib as a potential treatment for medullary thyroid cancer, known as the EXAM trial (Efficacy of XL184 (Cabozantinib) in Advanced Medullary Thyroid Cancer). We expect to complete the NDA filing in the second quarter of 2012.

We expect to expand the cabozantinib development program to other solid tumor indications, based on encouraging interim data that have emerged from the randomized discontinuation trial, or RDT, investigating cabozantinib in nine distinct tumor types, as well as other clinical trials. Objective tumor responses have been observed in patients treated with cabozantinib in 12 of 13 individual tumor types investigated to date, reflecting the broad potential clinical activity and commercial opportunity of this new product candidate. Interim data suggest that cabozantinib has shown novel activity against bone and soft tissue lesions in patients with CRPC. We have also observed resolution of metastatic bone lesions on bone scan in patients with metastatic breast cancer, renal cell carcinoma, thyroid cancer and melanoma. Interim data from the CRPC cohort of the RDT reported at the American Society of Clinical Oncology Annual Meeting in June 2011 demonstrated that in addition to improvement of bone lesions on bone scan observed in the majority (75%) of patients, 67% of patients with bone metastases and bone pain at baseline also experienced alleviation of pain. This observation has been corroborated in a non-randomized expansion cohort, or NRE, of CRPC patients in the RDT, which collected prospectively defined patient reported outcomes on pain and narcotic use. Interim data from the NRE reported at the AACR-NCI-EORTC Symposium on Molecular Targets and Cancer Therapeutics in November 2011 demonstrated that 48% of CRPC patients with moderate to severe pain in the NRE experienced durable pain reduction greater than or equal to 30%. The median best pain reduction was 46%. In addition, these interim data indicated that 56% of CRPC patients in the NRE with moderate to severe bone pain and on narcotics at baseline were able to reduce or discontinue narcotic medication. Lower starting doses of cabozantinib are being evaluated through a dose-ranging study in CRPC patients conducted through an investigator-sponsored trial, or IST. Preliminary data from this

dose-ranging IST demonstrate that a daily dose of 40 mg resulted in a rate of bone scan responses similar to that of a 100 mg daily dose used in the RDT and was associated with improved tolerability compared with the higher dose. In addition, preliminary data from a cohort of CRPC patients in the NRE treated at a daily dose of 40 mg demonstrate pain palliation responses consistent with observations at the 100 mg daily dose.

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We believe that cabozantinib s clinical profile is compelling and will allow commercial differentiation, assuming regulatory approval. Accordingly, it is a priority for us to generate additional data from the RDT as well as other ongoing exploratory clinical trials for cabozantinib in a broad range of tumor types, including ovarian cancer, melanoma, breast cancer, non-small cell lung cancer, hepatocellular cancer, renal cell carcinoma and differentiated thyroid cancer, to support further prioritization of our clinical and commercial options. We have launched two initiatives to expand the cabozantinib development program beyond our internal development efforts: our IST program and our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute s Cancer Therapy Evaluation Program, or NCI-CTEP. We launched the IST program in 2011, and it has already provided important interim data through the dose-ranging study described above. These data were important for dose selection in the COMET pivotal trial program, and we believe they will guide dose selection for a potential future trial to evaluate the ability of cabozantinib to prevent bone metastases in men with prostate cancer. Other important recently initiated ISTs include one in women with hormone receptor-positive metastatic breast cancer and bone metastases, a study evaluating cabozantinib in combination with abiraterone in CRPC patients, and a study evaluating cabozantinib in chemotherapy naïve CRPC patients. We plan to expand the IST program with new trials this year.

We entered into our CRADA with NCI-CTEP in November 2011, and on May 3, 2012 we announced that an initial program of twelve proposed clinical trials has been approved by us and NCI-CTEP under the CRADA, as follows:

- Phase 2 clinical trials in disease settings where there is substantial unmet medical need and in which cabozantinib has previously demonstrated clinical activity, consisting of randomized phase 2 clinical trials in first line renal cell carcinoma, second line hepatocellular carcinoma, platinum-resistant or refractory ovarian cancer and second line non-small cell lung cancer, and non-randomized phase 2 trials in ocular melanoma and non-small cell lung cancer. We believe that data from these phase 2 clinical trials would help prioritize future phase 3 pivotal trials of cabozantinib.

- Additional phase 2 clinical trials to explore cabozantinib s potential utility in additional tumor types, consisting of trials in endometrial cancer, bladder cancer and sarcoma. Positive results in these indications could lead to further study in randomized phase 2 or phase 3 clinical trials.

- Additional phase 1 clinical trials, consisting of a trial evaluating cabozantinib in combination with docetaxel in CRPC patients, a trial exploring the utility of combining cabozantinib with vemurafenib, a BRAF inhibitor, in patients with BRAF-mutated melanoma, and a trial to evaluate the safety and phamacokinetics of cabozantinib in pediatric malignancies.

An additional phase 2 clinical trial in second line differentiated thyroid cancer was approved by us and NCI-CTEP under the CRADA on May 3, 2012. Commencement of each of the proposed trials approved under the CRADA is subject to protocol development and satisfaction of certain other conditions. The proposed trials approved under the CRADA will be conducted under an investigational new drug application held by NCI-CTEP. We believe our CRADA reflects a major commitment by NCI-CTEP to support the broad exploration of cabozantinib s potential in a wide variety of cancers that have substantial unmet medical needs. Since NCI-CTEP provides funding for as many as 20 active clinical trials each year for a five year period, we believe the agreement will enable us to broadly expand the cabozantinib development program in a cost-efficient manner.

Collaborations

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Genentech, Inc. (a wholly- owned member of the Roche Group), GlaxoSmithKline, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for various compounds and programs in our portfolio. Pursuant to these collaborations, we have out-licensed compounds or programs to a partner for further development and commercialization, generally have no further unfunded cost obligations related to such compounds or programs and may be entitled to receive research funding, milestones and royalties or a share of profits from commercialization. Several of the out-licensed compounds are in multiple phase 2 studies and could potentially be of significant value to us if their development progresses successfully. With respect to our partnered compounds, we are eligible to receive potential milestone payments under our collaborations totaling approximately $3.1 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 44% are related to regulatory milestones and 46% are related to commercial milestones.

Certain Factors Important to Understanding Our Financial Condition and Results of Operations

Successful development of drugs is inherently difficult and uncertain. Our business requires significant investments in research and development over many years, often for products that fail during the research and development process. Our long-term prospects depend upon our ability, particularly with respect to cabozantinib, and the ability of our partners to successfully commercialize new therapeutics in highly competitive areas such as cancer treatment. Our financial performance is driven by many factors, including those described below.

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Clinical Development of Cabozantinib and Other Product Candidates

We are focusing our proprietary resources and development efforts on the development of cabozantinib. However, cabozantinib may fail to show adequate safety or efficacy in clinical testing. Furthermore, predicting the timing of the initiation or completion of clinical trials is difficult, and our trials may be delayed due to many factors, including factors outside of our control. The future development path of cabozantinib depends upon the results of each stage of clinical development. We expect to incur increased expenses for the development of cabozantinib as it advances in clinical development.

With the exception of activities related to cabozantinib, we are discontinuing efforts with respect to all of our compounds and programs that are not funded by partners pursuant to collaboration agreements and are considering collaborations or other external opportunities for the continued development of these compounds and programs. We expect discovery and clinical activities under various collaborations to continue to be funded by partners until we complete our contractual obligations.

Limited Sources of Revenues

We have no pharmaceutical products that have received marketing approval, and we have generated no revenues to date from the sale of such products. We do not expect to generate revenues from the sale of pharmaceutical products in the near term and expect that all of our near-term revenues, such as research and development funding, license fees and milestone payments and royalty revenues, will be generated from collaboration agreements with our current and potential future partners. Milestones under these agreements may be tied to factors that are outside of our control, such as significant clinical or regulatory events with respect to compounds or programs that have been out-licensed to our partners.

Liquidity

As of March 31, 2012, we had $332.1 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of $4.2 million and approximately $84.5 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately $65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

- the progress and scope of the development activity with respect to cabozantinib;
- whether we elect to pay cash or to issue shares of our common stock in respect of any conversion of our principal, prepayments or payments of interest in connection with the secured convertible notes we issued to entities affiliated with Deerfield Management Company, L.P., or Deerfield, under a note purchase agreement;
- whether we elect to prepay the amounts advanced under our loan from Silicon Valley Bank;
- the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;
- the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds or programs; and

whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular with respect to cabozantinib) that provide additional capital.

Our minimum liquidity needs are also affected by financial covenants in our loan and security agreement with Silicon Valley Bank and our note purchase agreement with Deerfield, as well as other factors, which are described under Liquidity and Capital Resources Cash Requirements .

Our ability to raise additional funds may be severely impaired if cabozantinib fails to show adequate safety or efficacy in clinical testing.

Deerfield Facility

On June 2, 2010, we entered into a note purchase agreement with Deerfield pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of $124.0 million initial principal amount of our secured convertible notes due June 2015 for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. The outstanding principal amount of the notes bears interest in the annual amount of $6.0 million, payable quarterly in arrears. We will be required to make mandatory

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prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of certain payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of $10.0 million. We may also prepay all or a portion (not less than $5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or mandatory prepayment in cash, subject to certain limitations (including a cap on the number of shares issuable under the note purchase agreement), we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first $10.0 million of mandatory prepayments required in 2013 and 2014) with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. Upon certain changes of control of our company, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than $400 million or a sale or transfer of more than 50% of our assets, Deerfield may require us to prepay the notes at the optional prepayment price, plus accrued and unpaid interest and any other accrued and reimbursable expenses, or the Put Price. Upon an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable.

We also entered into a security agreement in favor of Deerfield which provides that our obligations under the notes will be secured by substantially all of our assets except intellectual property. The note purchase agreement and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

Loan Agreement with Silicon Valley Bank

On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in the amount of $80.0 million. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement at all times in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank, bear interest at a per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement.

Restructurings

Since the inception of the 2010 and 2011 restructurings, we have recorded aggregate restructuring charges of $42.7 million, of which $20.2 million related to termination benefits and $22.5 million related to facility charges and the impairment of various assets. We had a restructuring credit of $0.2 million for the three months ended March 31, 2012. The credit was primarily due to asset auctions and direct sales of previously impaired assets, partially offset by facility-related charges due to the exit of all or portions of three of our South San Francisco buildings. The total outstanding restructuring liability is included in Current portion of restructuring and Long-term portion of restructuring on our Condensed Consolidated Balance Sheet and is based upon restructuring charges recognized as of March 31, 2012 in connection with the 2010 and 2011 restructurings. With respect to our restructurings, we expect to incur additional restructuring charges of $1.7 million relating to the previously mentioned exit and sublease of our South San Francisco facilities. These charges will be recorded through the end of 2017, or the end of the building lease terms.

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The remaining restructuring charges that we expect to incur in connection with the restructurings are subject to a number of assumptions, and actual results may materially differ. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructurings.

Critical Accounting Estimates

The preparation of the consolidated financial statements is in conformity with accounting principles generally accepted in the United States which require management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, clinical trial accruals, restructuring liability and stock option valuation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results could differ materially from these estimates.

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. We believe our critical accounting policies relating to revenue recognition, clinical trial accruals, restructuring liability and stock option valuation reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements. There have been no significant changes in our critical accounting policies and estimates during the three months ended March 31, 2012, as compared to the critical accounting policies and estimates disclosed in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2011.

Fiscal Year Convention

Exelixis adopted a 52- or 53-week fiscal year that ends on the Friday closest to December 31st. Fiscal year 2011, a 52-week year, ended on December 30, 2011, and fiscal year 2012, a 52-week year, will end on December 28, 2012. For convenience, references in this report as of and for the fiscal quarters ended April 1, 2011 and March 30, 2012, and as of the fiscal year ended December 30, 2011 are indicated as ended March 31, 2011 and 2012, and as ended December 31, 2011, respectively.

Results of Operations

Revenues

Total revenues by category, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended March 31,	
	2012	2011
Contract		
Research and development funding	$	$ 9.8
Milestones	3.8	2.6
License (1)	14.7	22.8
Collaboration reimbursement		0.7
Total revenues	$ 18.5	$ 35.9
Dollar change	$ (17.4)	
Percentage change	(48.5%)	

(1) Includes amortization of up-front payments.

Total revenues by customer, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended March 31,	
	2012	2011
Sanofi	$	$ 18.6
Bristol-Myers Squibb	7.8	16.8
Boehringer Ingelheim		0.5
Merck	10.7	
Total revenues	$ 18.5	$ 35.9
Dollar change	$ (17.4)	
Percentage change	(48.5%)	

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The decrease in revenues for the three months ended March 31, 2012, as compared to the prior year period, is primarily due to the transfer in April 2011 of substantially all development activities pertaining to XL147 and XL765 to Sanofi under our 2009 license agreement for these compounds, the termination in December 2011 of our 2009 collaboration with Sanofi for the discovery of inhibitors of phosphoinositide-3 kinase, or PI3K, and the termination of our 2008 agreement with Bristol Myers-Squibb for XL281 in October 2011. The decrease in revenues was partially offset by $10.7 million in revenue recognized under our agreement with Merck for our PI3K-d program signed in December 2011.

Research and Development Expenses

Total research and development expenses, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended March 31,	
	2012	2011
Research and development expenses	$ 33.1	$ 45.7
Dollar change	$ (12.6)	
Percentage change	(27.6%)	

The decrease for the three months ended March 31, 2012, as compared to the prior year period, resulted primarily from the following:

Clinical Trial Costs Clinical trial expenses, which include services performed by third-party contract research organizations and other vendors, decreased by $7.8 million, or 35%, primarily due to the transfer of XL147 and XL765 to Sanofi, as well as the gradual wind down of our EXAM trial. These decreases were partially offset by an increase in clinical trial activities for our COMET-2 trial and costs in preparation for the initiation of the COMET-1 trial.

General Corporate Costs There was a decrease of $2.0 million, or 26%, in the allocation of general corporate costs (such as facility costs, property taxes and insurance) to research and development, primarily as a result of a decrease in personnel as a result of our 2010 and 2011 restructurings, and the resulting decrease in costs to be allocated.

Personnel Personnel expense, which includes salaries, bonuses, related fringe benefits, recruiting and relocation costs, decreased by $1.5 million, or 15%, primarily due to the reduction in headcount resulting from our 2011 restructuring.

Stock-Based Compensation Stock-based compensation expense decreased by $0.6 million, or 31%, as a result of our reduction in headcount from our 2010 and 2011 restructurings.

We do not track total research and development expenses separately for each of our research and development programs. We group our research and development expenses into three categories: drug discovery, development and other. Our drug discovery group utilizes a variety of high-throughput technologies to enable the rapid discovery, optimization and extensive characterization of lead compounds such that we are able to select development candidates with the best potential for further evaluation and advancement into clinical development. Drug discovery expenses relate primarily to personnel expense, lab supplies and general corporate costs. Our development group leads the development and implementation of our clinical and regulatory strategies and prioritizes disease indications in which our compounds may be studied in clinical trials. Development expenses relate primarily to clinical trial, personnel and general corporate costs. The other category primarily includes stock-based compensation expense.

In addition to reviewing the three categories of research and development expenses described above, we principally consider qualitative factors in making decisions regarding our research and development programs. These factors include enrollment in clinical trials for our drug candidates, the results of and data from clinical trials, the potential indications for our drug candidates, the therapeutic and commercial potential for our drug candidates and competitive dynamics. We also make our research and development decisions in the context of our overall business strategy, which historically included the pursuit of commercial collaborations with major pharmaceutical and biotechnology companies for the development of our drug candidates. As noted under Overview, we are focusing our proprietary resources and development efforts exclusively on cabozantinib in order to maximize the therapeutic and commercial potential of this compound. Our strategy is to aggressively advance cabozantinib through development toward commercialization, and as a result, we expect nearly all of our future research and development

expenses to relate to the clinical development of cabozantinib.

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The expenditures summarized in the following table reflect total research and development expenses by category, including allocations for general and administrative expense (in millions):

	Three Months Ended March 31, 2012	2011	Inception to date (1)
Drug discovery	$ 3.7	$ 5.7	$ 460.1
Development	28.2	38.0	741.5
Other	1.2	2.0	102.0
Total	$ 33.1	$ 45.7	$ 1,303.6

(1) Inception is as of January 1, 2006, the date on which we began tracking research and development expenses by category.

While we do not track total research and development expenses separately for each program, beginning in fiscal 2006, we began tracking third party expenditures directly relating to each program as a way of monitoring external costs. Our third party research and development expenditures relate principally to our clinical trial and related development activities, such as preclinical and clinical studies and contract manufacturing, and represent only a portion of the costs related to each program. Third party expenditures for programs initiated prior to the beginning of fiscal 2006 have not been tracked from project inception, and therefore these expenditures from the actual inception for most of our programs are not available. We do not accumulate on a program-specific basis internal research and development expenses, such as salaries and personnel expenses, facilities overhead expenses and external costs not directly attributable to a specific project. Nevertheless, we believe that third party expenditures by program provide a reasonable estimate of the percentage of our total research and development expenses that are attributable to each such program. Under our current strategy, we are focusing our proprietary resources and development efforts exclusively on the late-stage development and commercialization of cabozantinib. As a result, as of March 31, 2012, approximately all of our external third party research and development expenditures were spent on this program. The expenses for the cabozantinib program were primarily included in the development category of our research and development expenses and exclude the impact of any amounts reimbursed by our partners.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. In general, we will incur increased research and development expenses for compounds that advance in clinical development, whereas expenses will end for compounds that do not warrant further clinical development.

We do not have reliable estimates of total costs for a particular drug candidate to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential products may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

General and Administrative Expenses

Total general and administrative expenses, as compared to the prior year period, were as follows (dollar amounts are presented in millions):

	Three Months Ended March 31, 2012	2011
General and administrative expenses	$ 7.9	$ 9.2
Dollar change	$ (1.3)	
Percentage change	(14.1%)	

General and administrative expenses consist primarily of personnel expenses, employee stock-based compensation expense, facility costs, legal patent costs and consulting and professional expenses, such as legal and accounting fees. The decrease in general and administrative expenses for the three months ended March 31, 2012, as compared to the prior year period, was primarily due to a decrease in rent, utilities and equipment, personnel costs, and stock compensation, as a result of our 2010 and 2011 restructurings. These decreases were offset by a decrease in allocation of general corporate costs to research and development as a result of the reduction in research and development headcount from our

2010 and 2011 restructurings.

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Restructuring Charge

The restructuring charge, as compared to the prior year period, was as follows (dollar amounts are presented in millions):

	Three Months Ended March 31, 2012	2011
Restructuring (credit) charge	$ (0.2)	$ 4.8
Dollar change	$ (5.0)	
Percentage change	(104%)	

We had a restructuring credit of $0.2 million for the three months ended March 31, 2012. The credit was primarily due to asset auctions and direct sales of previously impaired assets, partially offset by facility-related charges due to the exit of all or portions of three of our South San Francisco buildings. For the comparable period in 2011 the restructuring charge related primarily to facility charges associated with the exit and sublease of portions of one of our South San Francisco buildings. As a result of our 2010 and 2011 restructurings, we expect to incur additional restructuring charges of approximately $1.7 million, primarily related to facility costs, through the end of 2017, or the end of the building lease terms.

Total Other Income (Expense), Net

Total other income (expense), net as compared to the prior year period, was as follows (dollar amounts are presented in millions):

	Three Months Ended March 31, 2012	2011
Total other income (expense), net	$ (3.8)	$ (3.8)
Dollar change	$	
Percentage change		

Total other income (expense), net consists primarily of interest income earned on our marketable securities, offset by interest expense incurred on our notes payable, bank obligations, convertible notes and loan and our credit facility, which includes both a cash coupon component and non-cash accretion of interest under the Deerfield note purchase agreement. Total other income (expense), net for the three months ended March 31, 2012, as compared to the prior year period, was approximately the same, with no significant changes in interest income, interest expense or other income (expense), net.

Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities for the three months ended March 31, 2012 and 2011 (in thousands):

	Three Months Ended March 31, 2012	2011
Net loss	$ (26,151)	$ (27,490)
Adjustments to reconcile net loss to net cash used in operating activities	6,867	8,010
Changes in operating assets and liabilities	4,318	(23,796)
Net cash used in operating activities	(14,966)	(43,276)
Net cash used in investing activities	(52,278)	(31,502)
Net cash provided by financing activities	63,453	179,389
Net (decrease) increase in cash and cash equivalents	(3,791)	104,611
Cash and cash equivalents, at beginning of period	74,257	97,440

Cash and cash equivalents, at end of period	$ 70,466	$ 202,051

To date, we have financed our operations primarily through the sale of equity, receipts and loans from collaborators and banks, debt-financing arrangements and equipment financing facilities. We have also financed certain of our research and development activities under our agreements with various collaborators. As of March 31, 2012, we had $332.1 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of $4.2 million. As of March 31, 2012, approximately $84.5 million of cash and cash equivalents and marketable securities served as collateral under our loan and security agreement with Silicon Valley Bank.

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Operating Activities

Our operating activities used cash of $15.0 million for the three months ended March 31, 2012, compared to cash used of $43.3 million for the prior year period. Cash used by operating activities for the 2012 period related primarily to our net loss of $26.2 million, which was largely due to the development of cabozantinib, and to an $18.5 million reduction in deferred revenue, primarily due to the timing of revenue recognition of an up-front payment under our P13K-d license agreement with Merck entered into in December 2011. In addition, we paid $1.9 million of our restructuring liability and decreased our accounts payable and other accrued expenses by $2.7 million. Uses of cash were partially offset by the receipt of $27.3 million in cash relating to the termination of our 2009 discovery collaboration with Sanofi in December 2011 and the up-front payment from Merck under our P13K-d license agreement. In addition, we had non-cash charges totaling $5.8 million relating to stock-based compensation, depreciation and amortization and accretion of implied interest under our 2010 note purchase agreement with Deerfield.

Cash used by operating activities for the 2011 period related primarily to our net loss of $27.5 million, which was due to the development of cabozatinib and other compounds in various other discovery and development collaborations, and a $25.4 million reduction in deferred revenue, primarily due to the recognition of license revenue. In addition, we paid $1.5 million of our restructuring liability. These increases in cash used were partially offset by non-cash charges totaling $7.5 million relating to stock-based compensation, depreciation and amortization, accretion of implied interest under our 2010 note purchase agreement with Deerfield and impairment of assets due to our March and December 2010 restructurings. In addition, we had an increase in our accounts payable and other accrued liabilities of $4.4 million due to the timing of payments.

Investing Activities

Our investing activities used cash of $52.3 million for the three months ended March 31, 2012, compared to cash used of $31.5 million for the comparable period in 2011. Cash used by investing activities for the 2012 period was primarily due to the purchase of $113.4 million of marketable securities, less proceeds from the maturity of marketable securities of $60.3 million.

Cash used by investing activities for the 2011 period was primarily due to the purchase of $60.0 million of marketable securities, less proceeds from the maturity of marketable securities of $26.7 million and a decrease in restricted cash of $2.2 million.

Financing Activities

Our financing activities provided cash of $63.5 million for the three months ended March 31, 2012, compared to cash provided of $179.4 million for the comparable period in 2011. Cash provided by our financing activities for the 2012 period was due to the issuance of 12.7 million shares of common stock for net proceeds of $65.0 million, partially offset by cash used for principal payments on notes payable and bank obligations of $1.6 million.

Cash provided by our financing activities for the 2011 period was due to proceeds from the issuance of 17.3 million shares of common stock for net proceeds of $179.3 million and proceeds from the exercise of stock options of $3.8 million partially offset by cash used for principal payments on notes payable and bank obligations of $3.8 million.

Proceeds from collaboration loans and common stock issuances are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes and bank obligations, as discussed under Cash Requirements .

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Cash Requirements

We have incurred net losses since inception through 2010. We had a net loss of $26.2 million for the three months ended March 31, 2012. While we were in a net income position of $75.7 million for the year ended December 31, 2011, primarily as a result of the acceleration of revenue recognized under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011, we anticipate further net losses and negative operating cash flow for the foreseeable future. As of March 31, 2012, we had $332.1 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of $4.2 million and approximately $84.5 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately $65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the filing date of this report. However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

the progress and scope of the cabozantinib development program We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

repayment of the notes under our note purchase agreement with Deerfield The outstanding principal amount of the notes we issued to Deerfield bears interest in the annual amount of $6.0 million, payable quarterly in arrears. We are required to make certain mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 and may also prepay all or a portion (not less than $5.0 million) of the principal amount of the notes during their term. There can be no assurance that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank The principal amount outstanding under our term loan with Silicon Valley Bank, of $80.0 million, accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan. In accordance with the terms of the loan and security agreement, we are also required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement at all times in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds or programs;

whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib) that provide additional capital;

our ability to control costs;

our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;

the amount of our cash and cash equivalents and marketable securities that serve as collateral for bank lines of credit;

future clinical trial results;

our need to expand our product and clinical development efforts;

our ability to share the costs of our clinical development efforts with third parties;

the cost and timing of regulatory approvals;

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the cost of clinical and research supplies of our product candidates;

the effect of competing technological and market developments;

the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and

the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. As described below, the terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or levels of working capital:

Deerfield Our note purchase agreement with Deerfield contains an event of default that would be triggered if our cash and cash equivalents fall below $20.0 million as of December 28, 2012, subject to a cure period. Upon such an event of default, Deerfield may declare all or a portion of the Put Price to be immediately due and payable. Cash and cash equivalents for purposes of our note purchase agreement includes our total cash, cash equivalents and short-term and long-term marketable securities. As of March 31, 2012, our cash and cash equivalents were $332.1 million.

Silicon Valley Bank Our loan and security agreement with Silicon Valley Bank requires that we maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement at all times in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. If the balance on our deposit account(s) falls below the required level for more than 10 days, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us.

If we cannot raise additional capital in order to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at March 31, 2012 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the Securities and Exchange Commission on February 22, 2012. Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of March 31, 2012 and December 31, 2011. As of March 31, 2012 and December 31, 2011, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of $6.7 million and $7.2 million, respectively.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib and various other compounds in our pipeline at sites outside of the United States. Our agreements with the foreign sites that conduct these clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon

when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. As of March 31, 2012 and December 31, 2011, approximately $2.2 million and $2.8 million respectively of our clinical accrual balance related to foreign currencies. As of March 31, 2012 and December 31, 2011, an adverse change of one percentage point in the foreign currency exchange rates would have resulted in a net loss of $22,000 and $28,000, respectively.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on the evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) required by Rules 13a-15(b) or 15d-15(b) of the Exchange Act, our Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this report, our disclosure controls and procedures were effective.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the factors discussed elsewhere in this report and our other reports filed with the SEC, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.

We have marked with an asterisk (*) those risk factors below that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the Securities and Exchange Commission on February 22, 2012.

Risks Related to Our Need for Additional Financing and Our Financial Results

If additional capital is not available to us, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts and we may breach our financial covenants.*

We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development efforts; and
- commercialize our product candidates, if any such candidates receive regulatory approval for commercial sale.

As of March 31, 2012, we had $332.1 million in cash and cash equivalents, marketable securities and long-term investments, which included restricted cash and investments of $4.2 million and approximately $84.5 million of cash and cash equivalents and marketable securities that we are required to maintain on deposit with Silicon Valley Bank or one of its affiliates pursuant to covenants in our loan and security agreement with Silicon Valley Bank. In February 2012, we raised approximately $65 million in net proceeds from a public offering of our common stock. We anticipate that our current cash and cash equivalents, marketable securities, long-term investments and funding that we expect to receive from existing collaborators will enable us to maintain our operations for a period of at least 12 months following the filing date of this report.

However, our future capital requirements will be substantial, and we will need to raise additional capital in the future. Our capital requirements will depend on many factors, and we may need to use available capital resources and raise additional capital significantly earlier than we currently anticipate. These factors include:

the progress and scope of the cabozantinib development program We are focusing our proprietary resources and development efforts on cabozantinib, our most advanced product candidate, which is being studied in a variety of tumor types, with the goal of rapidly commercializing the compound. Cabozantinib is being evaluated in a broad development program encompassing multiple cancer indications. The current clinical program for cabozantinib is focused on the treatment of metastatic castration-resistant prostate cancer and medullary thyroid cancer and will be expanded to other solid tumor indications, based on encouraging interim data that have emerged from the RDT investigating cabozantinib in nine distinct tumor types and other clinical trials. In October 2011, we announced that our EXAM phase 3 clinical trial of

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cabozantinib in medullary thyroid cancer met its primary endpoint, and, in December 2011, the FDA granted us permission to initiate a rolling submission of an NDA for cabozantinib in medullary thyroid cancer. We initiated the submission in December 2011 by submitting to the FDA key parts of the NDA, including the preclinical information, and we expect to complete the NDA filing in the second quarter of 2012. Assuming priority review and approval of our NDA by the FDA, we currently anticipate a potential commercial launch of cabozantinib for the treatment of medullary thyroid cancer in the second half of 2012. In December 2011, we initiated our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer using an endpoint of pain reduction (COMET-2). We also plan to initiate a phase 3 pivotal trial in metastatic castration-resistant prostate cancer patients with an overall survival endpoint (COMET-1) in the second quarter of 2012 as part of our comprehensive development plan for cabozantinib in castration-resistant prostate cancer. We are also planning other potential pivotal trials in prostate cancer. Our development and commercialization plans for cabozantinib are dependent on the extent of our available financial resources. There can be no assurance that we will have sufficient financial resources independently or through other arrangements to fund the trials that are currently planned or in process, to fund other clinical trials that we may desire to initiate in the future or to fund commercialization efforts. If adequate funds are not available, we may be required to delay, discontinue or elect not to pursue one or more trials or commercialization efforts for cabozantinib;

repayment of the notes under our note purchase agreement with Deerfield On June 2, 2010, we entered into a note purchase agreement with Deerfield, pursuant to which, on July 1, 2010, we sold to Deerfield an aggregate of $124.0 million initial principal amount of our secured convertible notes, due June 2015, for an aggregate purchase price of $80.0 million, less closing fees and expenses. The outstanding principal amount of the notes bears interest in the annual amount of $6.0 million, payable quarterly in arrears. We will be required to make mandatory prepayments on the notes on an annual basis in 2013, 2014 and 2015 equal to 15% of specified payments from our collaborative arrangements received during the prior fiscal year, subject to a maximum annual prepayment amount of $27.5 million and, for payments due in January 2013 and 2014, a minimum prepayment amount of $10.0 million. We may also prepay all or a portion (not less than $5.0 million) of the principal amount of the notes at an optional prepayment price based on a discounted principal amount (during the first three years of the term, subject to a prepayment premium) determined as of the date of prepayment, plus accrued and unpaid interest, plus in the case of a prepayment of the full principal amount of the notes (other than prepayments upon the occurrence of specified transactions relating to a change of control or a substantial sale of assets), all accrued interest that would have accrued between the date of such prepayment and the next anniversary of the note purchase agreement. In lieu of making any optional or mandatory prepayment in cash, subject to specified limitations, we have the right to convert all or a portion of the principal amount of the notes into, or satisfy all or any portion of the optional prepayment amounts or mandatory prepayment amounts (other than the first $10.0 million of mandatory prepayments required in 2013 and 2014) with, shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the notes in cash, subject to specified limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. In the event the market price for our common stock is depressed or we do not have a sufficient number of authorized but unissued shares, we may not be able to convert the principal amount of the notes or satisfy our payment obligations in full using shares of our common stock due to restrictions in the agreement on the number of shares we may issue. In addition, the issuance of shares of our common stock to convert the notes or satisfy our payment obligations may result in significant dilution to our stockholders. As a result, we may need to obtain additional funding to satisfy our repayment obligations. There can be no assurance that we will have sufficient funds to repay the notes or satisfy our payment obligations under the note purchase agreement when due or that we will comply with the conditions to our ability to convert the principal amount of the notes into or satisfy our payment obligations with shares of our common stock;

repayment of our loan from Silicon Valley Bank On June 2, 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in an amount of $80.0 million. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. In accordance with the terms of the loan and security agreement, we are also required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement at all times in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. As a result, the proceeds of the term loan cannot be used to satisfy our other obligations without causing a default under our loan and security agreement with Silicon Valley Bank;

the level of payments received under existing collaboration agreements, licensing agreements and other arrangements;

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- the degree to which we conduct funded development activity on behalf of partners to whom we have out-licensed compounds or programs;
- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib) that provide additional capital;
- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the amount of our cash and cash equivalents and marketable securities that serve as collateral for bank lines of credit;
- future clinical trial results;
- our need to expand our product and clinical development efforts;
- our ability to share the costs of our clinical development efforts with third parties;
- the cost and timing of regulatory approvals;
- the cost of clinical and research supplies of our product candidates;
- the effect of competing technological and market developments;
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights; and
- the cost of any acquisitions of or investments in businesses, products and technologies.

We may seek to raise funds through the sale of equity or debt securities or through external borrowings. In addition, we may enter into additional strategic partnerships, collaborative arrangements or other strategic transactions. It is unclear whether any such partnership, arrangement or transaction will occur, on satisfactory terms or at all, or what the timing and nature of such a partnership, arrangement or transaction may be. The sale of equity or convertible debt securities in the future may be dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to curtail operations significantly or obtain funds by entering into financing, supply or collaboration agreements on unattractive terms or we may be required to relinquish rights to technology or product candidates or to grant licenses on terms that are unfavorable to us.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in agreements with third parties. The terms of our debt owed to Deerfield and Silicon Valley Bank each contain covenants requiring us to maintain specified cash balances or working capital. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we cannot raise additional capital in order to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender

exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

We have a history of net losses. We expect to continue to incur net losses, and we may not achieve or maintain profitability.*

We have incurred net losses since inception through 2010. We had a net loss of $26.2 million for the three months ended March 31, 2012 and as of March 31, 2012, we had an accumulated deficit of $1.1 billion. While we were in a net income position of $75.7 million for the year ended December 31, 2011, primarily as a result of the acceleration of revenue recognized under our 2008 collaboration agreement with Bristol-Myers Squibb that terminated in October 2011 and under our 2009 discovery collaboration agreement with Sanofi that terminated in December 2011, we anticipate further net losses and negative operating cash flow for the foreseeable future. We have not yet completed the development, including obtaining regulatory approval, of cabozantinib or any other product candidates and, consequently, have not generated revenues from the sale of pharmaceutical products. We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, research funding, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones, our collaborators fail to develop successful products or research funding we receive from collaborators decreases, we will not earn the revenues contemplated under such collaborative agreements. The amount of our net losses will depend, in part, on the rate of growth, if any, in our license and contract revenues and on the level of our expenses. These losses have had and will continue to have an adverse effect on our stockholders equity and working capital. Our research and development expenditures and general and administrative expenses have exceeded our revenues through 2010 and for the three months ended March 31, 2012, and we expect to spend significant additional amounts to fund the development of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

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We may not realize the expected benefits of our initiatives to control costs.

Managing costs is a key element of our business strategy. Consistent with this element of our strategy, during 2010, we implemented two restructurings that resulted in an overall reduction in our workforce by 386 employees. In March 2011, we implemented an additional restructuring that resulted in further reductions in 2011. Taking into consideration employees who have since been recalled, there has been an aggregate reduction in headcount from the 2010 and 2011 restructurings of 402 employees. We anticipate that we will incur additional restructuring charges through the end of 2017 in connection with the implementation of these restructurings.

As part of our restructurings, in 2011 we entered into two sublease agreements for portions of one of our buildings in South San Francisco, California. We are still assessing our ability to sublease portions of our facilities in light of the workforce reduction as well as the potential for sublease income. Estimates for sublease income would require significant assumptions regarding the time required to contract with subtenants, the amount of idle space we would be able to sublease and potential future sublease rates. If we are able to vacate portions of our facilities, we would need to continue to update our estimate of the lease exit costs in our financial statements until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

We are exposed to risks related to foreign currency exchange rates.

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of expenses incurred will be impacted by fluctuations in the currencies of those countries in which we conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our financial position and results of operations.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this report we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since March 31, 2012, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

Risks Related to Development of Cabozantinib

We are dependent on the successful development and commercialization of cabozantinib.

The success of our business is dependent upon the successful development and commercialization of cabozantinib. As part of our strategy, we intend to dedicate all of our proprietary resources to advance cabozantinib as aggressively as feasible. Our ability to realize the value of our investment is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. If we encounter difficulties in the development of cabozantinib due to any of the factors discussed in this Risk Factors section or otherwise, or we do not receive regulatory approval and are unable to commercialize cabozantinib, we will not have the resources necessary to continue our business in its current form.

Clinical testing of cabozantinib and other product candidates is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.

Clinical trials are inherently risky and may reveal that our product candidates are ineffective or have unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval.

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The results of preliminary studies do not necessarily predict clinical or commercial success, and later-stage clinical trials may fail to confirm the results observed in earlier-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events during, or as a result of, clinical testing that could delay or prevent commercialization of cabozantinib, including:

- cabozantinib may not prove to be efficacious or may cause, or potentially cause, harmful side effects;
- negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;
- our competitors may discover or commercialize other compounds or therapies that show significantly improved safety or efficacy compared to cabozantinib;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and
- regulators or institutional review boards may withhold authorization of, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

If we were to have significant delays in or termination of our clinical testing of cabozantinib as a result of any of the events described above or otherwise, our expenses could increase or our ability to generate revenues from cabozantinib could be impaired, either of which could adversely impact our financial results.

We have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of cabozantinib or meet current or future requirements of the FDA, including those identified based on our discussions with the FDA. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of cabozantinib or may not result in an approvable product. For example, as discussed in Risks Related to Regulatory Approval of Cabozantinib Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize this product candidate, we were not able to reach a timely agreement with the FDA under a Special Protocol Assessment, or SPA, on the proposed design and analyses of the COMET-2 trial.

Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of cabozantinib as a product candidate. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

- the number of patients that ultimately participate in the clinical trial;
- the duration of patient follow-up that is appropriate in view of the results;
- the number of clinical sites included in the trials; and

the length of time required to enroll suitable patient subjects.

Any delay could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly. Our partners under our collaboration agreements may experience similar risks with respect to the compounds we have out-licensed to them. If any of the events described above were to occur with such programs or compounds, the likelihood of receipt of milestones and royalties under such collaboration agreements could decrease.

If third parties upon which we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib.

We do not have the ability to independently conduct clinical trials for cabozantinib, and we rely on third parties we do not control such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize cabozantinib.

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We lack the capability to manufacture compounds for clinical trials and rely on third parties to manufacture cabozantinib, and we may be unable to obtain required material in a timely manner, at an acceptable cost or at a quality level required to receive regulatory approval.

We do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials. We rely on collaborators and third-party contractors to produce cabozantinib for clinical testing. These suppliers must comply with applicable regulatory requirements, including the FDA s current Good Manufacturing Practices, or GMP. Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality or in the quantity required to meet our development timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials may be delayed. Delays in preclinical or clinical testing could delay the initiation of clinical trials.

Our third-party manufacturers may not be able to comply with the GMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third-party manufacturers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse affect on our business.

Materials necessary to manufacture cabozantinib may not be available on commercially reasonable terms, or at all, which may delay its development and commercialization.

Some of the materials necessary for the manufacture of cabozantinib may, from time to time, be available either in limited quantities, or from a limited number of manufacturers, or both. Our contract manufacturers need to obtain these materials for our clinical trials and, potentially, for commercial distribution when and if we obtain marketing approval for cabozantinib. Suppliers may not sell us these materials at the time we need them or on commercially reasonable terms. If we are unable to obtain the materials needed to conduct our clinical trials, product testing and potential regulatory approval could be delayed, adversely affecting our ability to develop cabozantinib. Similarly, if we are unable to obtain critical manufacturing materials after regulatory approval has been obtained, the commercial launch of cabozantinib could be delayed or there could be a shortage in supply, which could materially affect our ability to generate revenues from sales of cabozantinib. If suppliers increase the price of manufacturing materials, the price for cabozantinib may increase, which may make it less competitive in the marketplace. If it becomes necessary to change suppliers for any of these materials or if any of our suppliers experience a shutdown or disruption at the facilities used to produce these materials, due to technical, regulatory or other reasons, it could harm our ability to manufacture cabozantinib.

Risks Related to Our Relationships with Third Parties

We are dependent upon our collaborations with major companies, which subjects us to a number of risks.

We have established collaborations with leading pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Genentech, Inc. (a wholly- owned member of the Roche Group), GlaxoSmithKline, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for the development and ultimate commercialization of a significant number of compounds generated from our research and development efforts. We continue to pursue collaborations for selected unpartnered preclinical and clinical programs and compounds. Our dependence on our relationships with existing collaborators for the development and commercialization of our compounds subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

- we are not able to control the amount and timing of resources that our collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;

- we may not be able to control the amount and timing of resources that our potential future collaborators may devote to the development or commercialization of drug candidates or to their marketing and distribution;

collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

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- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management s attention and resources;

- collaborators may experience financial difficulties;

- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- business combinations or significant changes in a collaborator s business strategy may adversely affect a collaborator s willingness or ability to complete its obligations under any arrangement;

- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;

- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;

- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and

- collaborations may be terminated (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011) or allowed to expire, which would delay, and may increase the cost of development of, our drug candidates.

If any of these risks materialize, our product development efforts could be delayed and otherwise adversely affected, which could adversely impact our business, operating results and financial condition.

If we are unable to continue current collaborations and achieve milestones or royalties, our revenues would suffer.

We have derived substantially all of our revenues to date from collaborative research and development agreements. Revenues from research and development collaborations depend upon continuation of the collaborations, the achievement of milestones and royalties we earn from any future products developed from the collaborative research. If we are unable to successfully achieve milestones or royalties, or our collaborators fail to develop successful products, we will not earn the revenues contemplated under such collaborative agreements.

If any of these agreements is terminated early (as occurred with respect to cabozantinib and XL281, which were previously subject to our 2008 collaboration agreement with Bristol-Myers Squibb, and with respect to our 2009 discovery collaboration with Sanofi, which was terminated in December 2011), whether unilaterally or by mutual agreement, our revenues could suffer. Most of our collaboration agreements contain early termination provisions. In addition, from time to time we review and assess certain aspects of our collaborations, partnerships and agreements and may amend or terminate, either by mutual agreement or pursuant to any applicable early termination provisions, such collaborations, partnerships or agreements if we deem them to be no longer in our economic or strategic interests. We may not be able to enter into new collaboration agreements on similar or superior financial terms to offset the loss of revenues from the termination or expiration of any of our existing or recently terminated arrangements.

We may be unable to establish collaborations for selected preclinical and clinical compounds.

Our strategy includes the pursuit of new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time consuming to negotiate and document. We may not be able to negotiate additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to negotiate additional collaborations, we may not be able to realize value from a particular drug candidate, particularly those drug candidates as to which we believe a broad development program is appropriate or for which we have determined not to continue to utilize our own resources to develop. As a result, our revenues, capital resources and product development efforts could be adversely affected.

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Risks Related to Regulatory Approval of Cabozantinib

Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize this product candidate.

Cabozantinib, as well as the activities associated with the research, development and commercialization of the product candidate, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for cabozantinib would prevent us from commercializing this product candidate. We have not received regulatory approval to market cabozantinib in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Before an NDA can be submitted to the FDA, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

We are conducting our EXAM phase 3 trial of cabozantinib as a potential treatment for medullary thyroid cancer under a SPA with the FDA. A SPA is designed to facilitate the FDA s review and provide feedback on the proposed design and size of clinical trials that are intended to form the primary basis for determining a product candidate s efficacy. If agreement is reached with the FDA, a SPA agreement documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of an NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product candidate s safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding the SPA. Our rolling NDA based on the EXAM results may not receive priority review and may be subject to delay or lack of approval, including delay or lack of approval based on potential feedback from an FDA Advisory Committee.

In December 2011, we initiated COMET-2, our first phase 3 pivotal trial of cabozantinib in patients with metastatic castration-resistant prostate cancer, with pain response as the primary efficacy endpoint for the trial. We were not able to reach a timely agreement with the FDA under a SPA on the proposed design and analysis of the COMET-2 trial. We originally submitted the proposed protocol for this trial using primary endpoints of pain reduction and bone scan response to the FDA in June 2011 with a request for a SPA. The FDA s final response prior to our discontinuation of the SPA process, which we received in October 2011, raised the following concerns regarding the COMET-2 trial design in the context of its consideration of a SPA for the trial, among other comments:

- A concern about the ability to maintain blinding of the trial due to differences in toxicity profiles between cabozantinib and mitoxantrone.
- A view that the assumed magnitude of pain improvement is modest and could represent a placebo effect or be attained with less toxicity by opioid therapy.
- A view that symptomatic improvement should be supported by evidence of anti-tumor activity, an acceptable safety profile and lack of survival decrement. The FDA also expressed the view that if the effect that we believe cabozantinib will have on pain is mediated by anti-tumor activity, that anti-tumor activity should translate into an improvement in overall survival.
- A recommendation that if we use pain response as a primary efficacy endpoint, that we conduct two adequate and well-controlled trials to demonstrate effectiveness as, according to the FDA, a conclusion based on two persuasive studies will always be more secure. The FDA advised that for a single randomized trial to support a new drug application, the trial must be well designed, well conducted, internally consistent and provide statistically persuasive efficacy findings so that a second trial would be ethically or practically impossible to perform.

In the context of its consideration of a SPA for the COMET-2 trial, the FDA also recommended that overall survival be the primary efficacy endpoint. The final FDA response prior to our discontinuation of the SPA process stated that we could choose to conduct the trial in the absence of a SPA agreement. We elected to proceed with initiation of the COMET-2 trial and the planned COMET-1 trial, and to discontinue further attempts to secure a SPA agreement with respect to the COMET-2 trial. We expect to initiate the COMET-1 trial in the second quarter of 2012. We initiated the COMET-2 trial in December 2011.

Any clinical trial may fail to produce results satisfactory to the FDA. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA (regardless of prior receipt of a SPA) or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib.

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In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during the development or approval periods of cabozantinib may cause delays in the approval or rejection of an application.

Even if the FDA or a comparable authority in another country approves cabozantinib, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of cabozantinib and may impose ongoing requirements for post- approval studies, including additional research and development and clinical trials. These agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Risks Related to Commercialization of Cabozantinib

The commercial success of cabozantinib will depend upon the degree of market acceptance of the product candidate among physicians, patients, health care payors, private health insurers and the medical community.

Our ability to commercialize cabozantinib will be highly dependent upon the extent to which the product candidate gains market acceptance among physicians; patients; health care payors, such as Medicare and Medicaid; private health insurers, including managed care organizations and group purchasing organizations, and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate adequate product revenues, if at all, and we may not become profitable. The degree of market acceptance of cabozantinib, if approved for commercial sale, will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;
- the existence of any significant side effects of cabozantinib, as well as their severity in comparison to those of any competing products;
- potential advantages or disadvantages in relation to alternative treatments;
- indications for which cabozantinib is approved;
- the ability to offer cabozantinib for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell cabozantinib, we may be unable to generate product revenues.

We have no experience as a company in the sales and distribution of pharmaceutical products and do not have a sales organization. Developing a sales force could be expensive and time-consuming, could delay any product launch, including our potential launch of cabozantinib for the treatment of medullary thyroid cancer, and we may never be able to develop this capacity. To the extent that we enter into arrangements with third parties to provide sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell cabozantinib ourselves. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues.

If we are unable to obtain adequate coverage and reimbursement from third-party payors for cabozantinib, our revenues and prospects for profitability will suffer.

Our ability to commercialize cabozantinib will be highly dependent on the extent to which coverage and reimbursement for the product candidate will be available from third-party payors, including governmental payors, such as Medicare and Medicaid, and private health insurers. Many patients will not be capable of paying themselves for cabozantinib and will rely on third-party payors to pay for, or subsidize, their medical needs. If third-party payors do not provide coverage or reimbursement for cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payors provide some coverage or reimbursement for cabozantinib, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

Another factor that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation, which would allow direct reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, it could decrease the price we receive for cabozantinib, thereby negatively affecting our revenues and prospects for profitability.

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In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement and/or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of cabozantinib to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of cabozantinib. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use cabozantinib. Cost-control initiatives could decrease the price we might establish for cabozantinib, which would result in lower product revenues to us.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell cabozantinib profitably.

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the U.S. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for branded and generic drugs, respectively;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning in 2011;

- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting any transfer of value made or distributed to prescribers and other healthcare providers, effective March 30, 2013, and reporting any investment

interests held by physicians and their immediate family members during the preceding calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a licensure framework for follow-on biologic products; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The United States Supreme Court has accepted petitions to hear a constitutional challenge to the PPACA in 2012. If the Supreme Court rules that the PPACA is unconstitutional, our expenditures in preparation for the PPACA could go unused, we could require new expenditures to adjust to the new competitive environment, and new legislation could later become law that could adversely affect the pharmaceutical industry.

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We anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We also cannot be certain that cabozantinib will successfully be placed on the list of drugs covered by particular health plan formularies, nor can we predict the negotiated price for cabozantinib, which will be determined by market factors. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If cabozantinib is not included on these preferred drug lists, physicians may not be inclined to prescribe it to their Medicaid patients, thereby diminishing the potential market for cabozantinib.

As a result of the PPACA and the trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may use tiered reimbursement and may adversely affect demand for our products by placing them in an expensive tier. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse for newly-approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payors outside of the United States for coverage and reimbursement of cabozantinib. We also anticipate pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

Our competitors may develop products and technologies that make cabozantinib obsolete.

The biotechnology industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. Some of our competitors are further along in the development of their products than we are. In addition, delays in the development of cabozantinib could allow our competitors to bring products to market before us, which would impair our ability to commercialize cabozantinib. Our future success will depend upon our ability to maintain a competitive position with respect to technological advances. Any products that are developed through our technologies will compete in highly competitive markets. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and marketing capabilities than we do. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development that may compete with cabozantinib. In addition, if cabozantinib is successfully developed, it may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications. Examples of potential competition for cabozantinib include AstraZeneca s RET, VEGFR and EGFR inhibitor, vandetanib, Algeta s development-stage alpha-pharmaceutical, Alpharadin (Radium-223), other VEGF pathway inhibitors, including Genentech s bevacizumab, and other MET inhibitors, including Pfizer s crizotinib, ArQule s tivantinib (ARQ197), GlaxoSmithKline s foretinib (XL880) and Genentech s onartuzumab.

We may not be able to manufacture cabozantinib in commercial quantities, which would prevent us from commercializing the product candidate.

To date, cabozantinib has been manufactured in small quantities for preclinical and clinical trials. If cabozantinib is approved by the FDA or other regulatory agencies for commercial sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity, whether in collaboration with third-party manufacturers or on our own, for cabozantinib in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for cabozantinib, the regulatory approval or commercial launch of the product candidate may be delayed or there may be a shortage in supply. Cabozantinib requires precise, high-quality manufacturing. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

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Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biotechnology companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. In addition, because patent applications can take many years to issue, there may be pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for these inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies. Other parties have filed, and in the future are likely to file, patent applications covering genes and gene fragments, techniques and methodologies relating to model systems and products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to obtain or could require substantial time and expense.

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

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We may be subject to damages resulting from claims that we, our employees or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and independent contractors were previously employed at universities, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert management s attention. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our ability to commercialize certain product candidates, which could severely harm our business.

Risks Related to Employees and Location

The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to expand our operations.

We are highly dependent upon the principal members of our management and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we may not have sufficient personnel to execute our business plan. Retaining and, where necessary, recruiting qualified clinical and scientific personnel will be critical to support activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. The restructurings that we implemented in 2010 and 2011 could have an adverse impact on our ability to retain and recruit qualified personnel. Competition is intense for experienced clinical personnel, and we may be unable to retain or recruit clinical personnel with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible. Further, all of our employees are employed at will and, therefore, may leave our employment at any time.

Our collaborations with outside scientists may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working may be significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

Our headquarters are located near known earthquake fault zones, and the occurrence of an earthquake or other disaster could damage our facilities and equipment, which could harm our operations.

Our headquarters are located in South San Francisco, California, and therefore our facilities are vulnerable to damage from earthquakes. We do not carry earthquake insurance. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events since any insurance we may maintain may not be adequate to cover our losses. If any disaster were to occur, our ability to operate our business at our facilities could be seriously, or potentially completely, impaired. In addition, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Security breaches may disrupt our operations and harm our operating results.

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets could have a material adverse impact on our business, operating results and financial condition.

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Risks Related to Environmental and Product Liability

We use hazardous chemicals and radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and such liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

In addition, our collaborators may use hazardous materials in connection with our collaborative efforts. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials used by these parties. Further, we may be required to indemnify our collaborators against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations.

We face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product we or our collaborators develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to trial participants and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10.0 million per occurrence and $10.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for cabozantinib, we intend to expand our insurance coverage to include the sale of commercial products, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

Risks Related to Our Common Stock

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline, causing investor losses.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results to volatility, including:

- the scope of our research and development activities;
- recognition of up-front licensing or other fees or revenues;
- payments of non-refundable up-front or licensing fees, or payment for cost-sharing expenses, to third parties;
- acceptance of our technologies and platforms;

the success rate of our efforts leading to milestone payments and royalties;

the introduction of new technologies or products by our competitors;

the timing and willingness of collaborators to further develop or, if approved, commercialize our product out-licensed to them;

our ability to enter into new collaborative relationships;

the termination or non-renewal of existing collaborations;

the timing and amount of expenses incurred for clinical development and manufacturing cabozantinib;

adjustments to expenses accrued in prior periods based on management s estimates after the actual level of activity relating to such expenses becomes more certain;

the impairment of acquired goodwill and other assets;

the impact of our restructurings; and

general and industry-specific economic conditions that may affect our collaborators research and development expenditures.

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A large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed in the short term. If we fail to achieve anticipated levels of revenues, whether due to the expiration or termination of existing contracts, our failure to obtain new contracts, our inability to meet milestones or for other reasons, we may not be able to correspondingly reduce our operating expenses, which could significantly harm our operating results for a particular fiscal period.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. As a result, in some future quarters, our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our common stock.

Our stock price may be extremely volatile.

The trading price of our common stock has been highly volatile, and we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following, many of which we cannot control:

- adverse results or delays in our or our collaborators clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators or our competitors clinical trials;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for one or more of our out-licensed programs and compounds;
- actions taken by regulatory agencies with respect to cabozantinib or our clinical trials for cabozantinib;
- the announcement of new products by our competitors;
- quarterly variations in our or our competitors results of operations;
- developments in our relationships with our collaborators, including the termination or modification of our agreements;
- conflicts or litigation with our collaborators;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;

financing transactions;

developments in the biotechnology or pharmaceutical industry;

sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;

departures of key personnel or board members;

developments concerning current or future collaborations;

FDA or international regulatory actions;

third-party reimbursement policies;

disposition of any of our subsidiaries, technologies or compounds; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs and divert management s attention and resources, which could have a material and adverse effect on our business.

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Future sales of our common stock may depress our stock price.

If our stockholders sell substantial amounts of our common stock (including shares issued upon the exercise of options and warrants or upon vesting of restricted stock units and shares issued under our employee stock purchase plan) in the public market, the market price of our common stock could fall. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

Some of our existing stockholders can exert control over us, and their interests could conflict with the best interests of our other stockholders.

Due to their combined stock holdings, our officers, directors and principal stockholders (stockholders holding more than 5% of our common stock), acting together, may be able to exert significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in control of our company, even when a change may be in the best interests of our stockholders. In addition, the interests of these stockholders may not always coincide with our interests as a company or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that would not be widely viewed as beneficial.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent or deter attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of our company, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the inability of our stockholders to call special meetings of stockholders;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;
- limitations on the removal of directors; and
- advance notice requirements for director nominations and stockholder proposals.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The table below provides information on our repurchases of our common stock, all of which were to satisfy tax obligations upon the vesting of restricted stock units under our 2000 Equity Incentive Plan and 2010 Inducement Award Plan. We may make similar repurchases in the future to satisfy employee tax obligations upon the vesting of restricted stock units.

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Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
Month #1 (December 31, 2011 January 27, 2012)				
Month #2 (January 28, 2012 March 2, 2012)	111,248	$5.80		
Month #3 (March 3, 2012 March 30, 2012)	979	$5.31		

ITEM 6. EXHIBITS

(a) Exhibits

The exhibits listed on the accompanying exhibit index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 3, 2012

EXELIXIS, INC.

/s/ Frank Karbe
Frank Karbe

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation by Reference Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.1	3/10/2010	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Exelixis, Inc.	10-K	000-30235	3.2	3/10/2010	
3.3	Amended and Restated Bylaws of Exelixis, Inc.	8-K	000-30235	3.1	12/5/2011	
4.1	Specimen Common Stock Certificate.	S-1, as amended	333-96335	4.1	2/7/2000	
4.2	Form of Warrant, dated June 10, 2009, to purchase 500,000 shares of Exelixis, Inc. common stock in favor of Symphony Evolution Holdings LLC.	10-Q, as amended	000-30235	4.4	7/30/2009	
4.3*	Warrant Purchase Agreement, dated June 9, 2005, between Exelixis, Inc. and Symphony Evolution Holdings LLC.	10-Q	000-30235	10.8	8/9/2005	
4.4*	Form Warrant to Purchase Common Stock of Exelixis, Inc. issued or issuable to Deerfield Private Design Fund, L.P., Deerfield Private Design International, L.P., Deerfield Partners, L.P. and Deerfield International Limited	8-K	000-30235	4.9	6/9/2008	
4.5	Form of Common Stock Agreement and Warrant Certificate	S-3, as amended	333-158792	4.17	4/24/2009	
4.6	Form of Preferred Stock Agreement and Warrant Certificate	S-3, as amended	333-158792	4.18	4/24/2009	
4.7	Form of Debt Securities Warrant Agreement and Warrant Certificate	S-3, as amended	333-158792	4.19	4/24/2009	
4.8	Form of Senior Debt Indenture	S-3, as amended	333-158792	4.13	5/28/2009	
4.9	Form of Subordinated Debt Indenture	S-3, as amended	333-158792	4.14	5/28/2009	
4.10	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design International, L.P.	10-Q	000-30235	10.1 (Exhibit A-1)	8/5/2010	
4.11		10-Q	000-30235	10.1	8/5/2010	

	Form of Note, dated July 1, 2010, in favor of Deerfield Private Design Fund, L.P.			(Exhibit A-2)	
10.1	Compensation Information for Named Executive Officers.	8-K	000-30235	10.1	2/7/2012

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Exhibit Number	Exhibit Description	Incorporation by Reference Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a).					X
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of Exelixis, Inc., as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS#	XBRL Instance Document					X
101.SCH#	XBRL Taxonomy Extension Schema Document					X
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB#	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document					X

* Confidential treatment granted for certain portions of this exhibit.
This certification accompanies this Quarterly Report on Form 10-Q, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Exelixis, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

\# Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.